

### **REMARKS**

Upon entry of the present amendment, claims 7-9 and 12-13 are pending in the instant application. Claims 11 and 14 have been cancelled without prejudice or disclaimer. Claims 7-9 have been amended. Support for the claim amendments presented herein is found throughout the specification and in the claims as originally filed. For example, support for the methods of screening a patient for a colorectal cancer or a colorectal precancer recited by amended claims 7-9 is found at least at page 3, lines, 19-26; at page 4, lines 5-24; at page 5, lines 3-5 and lines 18-26; at page 7, line 17 through page 8, line 9; at page 11, lines 1-7 and lines 23-26; at page 12, lines 25-28; at page 14, lines 9-27; in Examples 1 and 2 at pages 14-17; and in claims 10, 11 and 14 as originally filed. Accordingly, no new matter has been added by these amendments.

### **Claim rejections under 35 U.S.C. § 112, first paragraph**

Claims 7-14 have been rejected under 35 U.S.C. §112, first paragraph for lack of enablement. According to the Examiner:

the specification, while being enabling for methods for screening a patient for colorectal cancer or precancer by determining in fecal matter a ratio of between a first amount of a nucleic acid of a length greater than 200 base pairs and a second amount of a nucleic acid of a length less than said long nucleic acid, does not reasonably provide enablement for the detection of other types of cancers or precancers or the use of tissues or body fluids other than fecal matter or methods which do not specify the length of the nucleic acids that are detected. (Office Action, page 2).

Independent claims 7-9 (and their respective dependent claims) have been amended herein. In particular, claim 7 has been amended to recite a method for screening a patient for a colorectal cancer or a colorectal precancer by detecting, in a patient stool sample containing exfoliated cells, a long nucleic acid fragment of a length greater than 200 base pairs, wherein a fragment of the long nucleic acid having a length less than 200 base pairs is expected to be present in a stool sample in a healthy patient, such that the presence of the long nucleic acid being a positive screen for a colorectal cancer or precancer.

Amended claim 8 is directed to a method for screening a patient for a colorectal cancer or a colorectal precancer by detecting in a patient stool sample containing exfoliated cells or cellular debris a first amount of a long nucleic acid of a length greater than 200 base pairs in length; wherein the long nucleic acid is present in both normal and cancerous or precancerous

cells; (ii) comparing the first amount of long nucleic acid in the patient stool sample to a second amount of the long nucleic acid present in a sample from a patient free of colorectal cancer or precancer; (iii) determining whether the first amount of long nucleic acid exceeds the second amount of long nucleic acid in the sample from a patient free of colorectal cancer or precancer; and (iv) identifying a positive screen for a colorectal cancer or precancer if the first amount of long nucleic acid in the patient stool sample does exceed the second amount of long nucleic acid in the sample from a patient free of colorectal cancer or precancer.

As amended, claim 9 recites a method for screening a patient for a colorectal cancer or a colorectal precancer by (i) determining in a patient stool sample that contains exfoliated cells or cellular debris a first amount of long nucleic acid of a length greater than 200 base pairs; (ii) determining in the stool sample a second amount of nucleic acid of a length less than the long nucleic acid; (iii) determining a ratio between the first amount and the second amount; and (iv) identifying a positive screen for a colorectal cancer or precancer if the ratio exceeds a threshold ratio for patients who do not have a colorectal cancer or precancer.

Thus, the amended claims are directed to methods of screening a patient for a colorectal cancer or a colorectal precancer by detecting, in a stool sample, the presence of a long nucleic acid of a length greater than 200 base pairs. As such, these claims are not directed to the identification of any cancer or precancer in any bodily tissue or fluid by detecting a DNA of any length greater than a length expected to be found in a sample from a healthy patient.


Applicants submit that the methods recited by the amended claims are described throughout the specification, *e.g.*, in Examples 1 and 2 at pages 14-17, in such a way as to enable a person of ordinary skill in the art to practice these methods without undue experimentation. Accordingly, the scope of the amended claims is commensurate with the disclosure in the instant application. In fact, the Examiner has acknowledged on page 2 of the Office Action that the specification is enabling for such methods.

Applicants, therefore, request that the Examiner withdraw this rejection.

### CONCLUSION

On the basis of the foregoing amendments and arguments, Applicant submits that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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